

**Notice of Allowability**

Application No.

09/782,953

Examiner

SAMUEL W. LIU

Applicant(s)

WILLIAMS ET AL.

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to appeal brief filed 5/6/08.
2. ☒ The allowed claim(s) is/are 59,61,62 and 70.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All   b) ☐ Some\*   c) ☐ None   of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |  |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Notice of Informal Patent Application                      |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br>Paper No./Mail Date _____    | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                    |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance   |
|  | 9. <input type="checkbox"/> Other _____.   |

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### DETAILED ACTION

Applicants' amendments filed 5/31/07 which amends claims 59 and 61-62 (before "Appeal brief" filed 5/6/08), and cancels claims 1-58, 60 and 63-69 has been entered. The applicants' request filed 5/6/08 for extension of time of three months has been entered. Claims 59, 61-62 and 70 are examined in this Office action.

#### EXAMINER'S AMENDMENT

An Examiner's Amendment to the record appears below. Should the change and/or additions be unacceptable to Applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than payment of the Issue Fee.

Authorization for this Examiner's Amendment was given in a telephone interview with Steven L. Highlander on 7/7/08. Applicants agree the Examiner proposed amendment to claims 59 and 70.

#### Amendments to the specification:

Change the title of this invention to: "Methods relating to muscle selective calcineurin interactive protein (MCIP)".

#### Amendments to the claim:

Rewrite Claim 59 as (*Amended*): A method of modulating muscle cell growth in striated muscle cells in a human subject comprising:

- (a) identifying a human subject in need of striated muscle cell growth modulation;
  - (b) ~~selecting a small molecule for its ability to modulate~~ assaying a small molecule for its ability to modulate Muscle Selective Calcineurin Interacting Protein (MCIP1) expression; and
  - (c) administering said small molecule which is shown to modulate MCIP1 expression in step (b) to said human subject,
- whereby administration of said ~~modulator~~ small molecule results in modulation of striated muscle cell growth by modulating said MCIP1 expression in said human subject.

Rewrite Claim 70 as (*Amended*): The method of claim 59, further comprising administering to said human subject a ~~second~~ pharmaceutical agent used to treat cardiac disease.

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The following is an examiner's statement of reasons for allowance:

The rejections under 35 USC 102(b) of (i) claims 59, 62 and 70 by Sussman et al.; (ii) claims 59, 61 and 70 by Cavazza C.; (iii) claims 59 and 62 by Lanza et al.; (iv) claims 59, 62 and 70 by Selawry et al. are withdrawn in light of the amended claim 59 and dependent claims therefrom are directed to a method of modulating striated muscle cell growth in a human comprising steps of identifying said human subject in need, and assaying for a small molecule capable of modulating MCIP1 expression wherein the modulation of MCIP expression in said "assaying" is not considered here to be a mechanistic step but rather an actual step required necessary for the claimed method. None of references (i)-(iv) teaches the method's steps thereof. The rejection under 35 USC 103(a) of claims 59, 61 and 62 by Chin et al. is withdrawn similarly in light of how Chin et al. do not teach or suggest the steps of the claimed method as discussed above. Also, the rejection under 35 USC 112, second paragraph, of claims 59, 61-62 and 70 is withdrawn in light of that the metes and bounds of "small molecule" are not ambiguous in the relative art, and in light of that the above amendment of claim 70 obviates the indefiniteness rejection of "a second pharmaceutical agent".

Therefore, claims 59, 61-62 and 70 are allowed.

Any comments considered necessary by applicants must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Samuel Wei Liu, Ph.D. whose telephone number is (571) 272-0949. The Examiner can normally be reached daily except alternate Fridays from 8:30 A.M. to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Kathleen Kerr Bragdon, can be reached at (571) 272-0931. The official fax number for Technology Center 1600 is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

/Samuel W Liu, Ph.D./  
Examiner, Art Unit 1656  
July 15, 2008

/Kathleen Kerr Bragdon/  
Supervisory Patent Examiner, Art Unit 1656